Decision Memo for Ventricular Assist Devices (VADs) as a Bridge to Heart Transplantation (CAG-00162N)

Decision Summary

CMS intends to issue an NCD which indicates that, consistent with CIM §65-15, ventricular assist devices, when used as a bridge to transplant, are reasonable and necessary. CIM §35-87 will be modified to remove the prohibition against this indication. Other indications for or prohibitions against the use of ventricular assist devices in either CIM §65-15 or 35-87 are not affected by this determination.

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Decision Memo

This decision memorandum does not constitute a national coverage determination (NCD). It states CMS's intent to issue an NCD. Prior to any new or modified policy taking effect, CMS must first issue a manual instruction giving specific directions to our claims-processing contractors. That manual issuance, which includes an effective date, is the NCD. If appropriate, the Agency must also change billing and claims processing systems and issue related instructions to allow for payment. The NCD will be published in the Medicare Coverage Issues Manual. Policy changes become effective as of the date listed in the transmittal that announces the Coverage Issues Manual revision.

TO: Administrative File: CAG #00162N

Ventricular Assist Devices (VADs) Used as a Bridge to Heart Transplantation

FROM:

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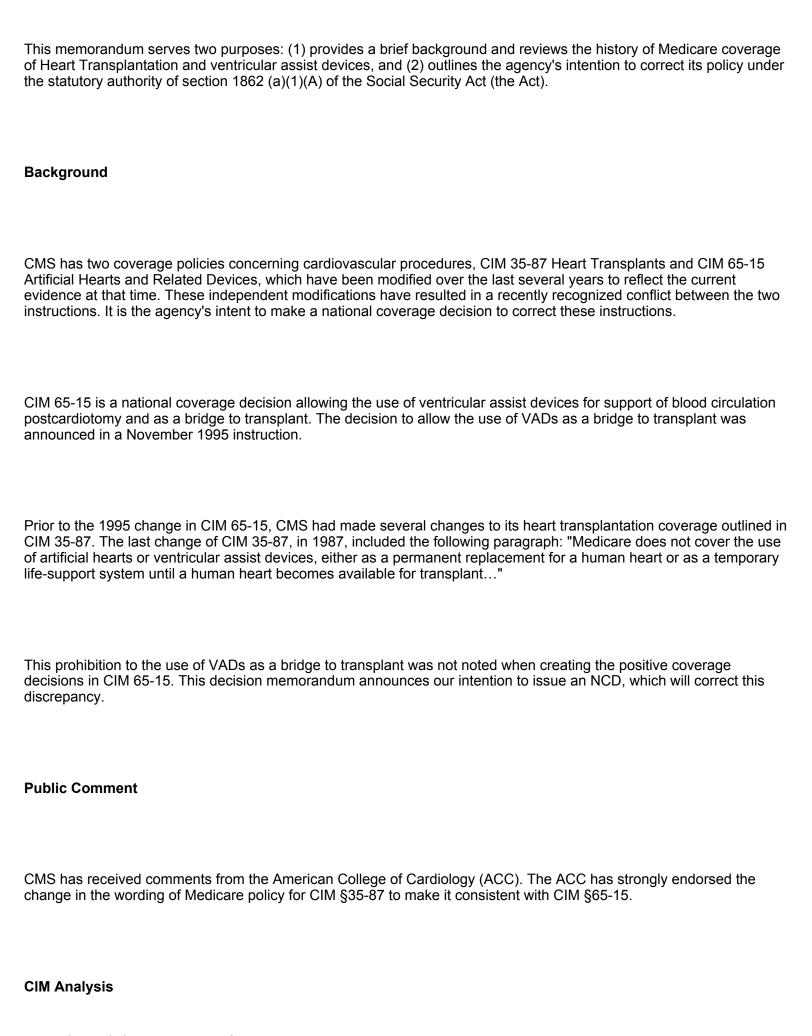
Madeline Ulrich, MD Medical Officer, CAG

SUBJECT: Coverage Decision Memorandum for Ventricular Assist Devices (VADs) Used as a Bridge to Heart

Transplantation to correct CIM 35-87 which incorrectly contradicts CIM 65-15 for using VADs as a bridge

to transplant.

DATE: October 30, 2002



The older NCD, CIM §35-87, was developed based upon the scientific evidence at that time that did not demonstrate the clinical effectiveness of VADs. The subsequent NCD, CIM §65-15, used more current evidence that did demonstrate the clinical effectiveness of VADs as a bridge to transplant. An unintentional procedural error left CIM §35-87 unchanged and in conflict with the newer CIM §65-15. There is no additional evidence since the publication of CIM §65-15 that would indicate that VADs are no longer clinically effective. Therefore, CMS determines that VADs as a bridge to transplant are reasonable and necessary and the prohibition in CIM §35-87 should be removed.

Decision

CMS intends to issue an NCD which indicates that, consistent with CIM §65-15, ventricular assist devices, when used as a bridge to transplant, are reasonable and necessary. CIM §35-87 will be modified to remove the prohibition against this indication. Other indications for or prohibitions against the use of ventricular assist devices in either CIM §65-15 or 35-87 are not affected by this determination.

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